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10/566,666	01/27/2006	Takashi Shirahata	1141/75776	5938

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EXAMINER	
CONWAY, THOMAS A	
ART UNIT	PAPER NUMBER
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,666	SHIRAHATA ET AL.	
	Examiner	Art Unit	
	THOMAS A. CONWAY	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Examiner's responses to Applicant's remark

1. Applicants' amendments filed on 11/30/2009 have been entered and made of record.

2. Applicants' amendments have been fully considered. The amendments overcome the following set forth in non-final office action, mailed on 9/1/2009:

a. Objection to the Specification

b. Rejection of claims 1 and 11 under 35 USC 112, 1st ¶

c. Rejection of claims 1-5, 7, 11-16 and 18 under 35 USC 112, 2nd ¶

d. Rejection of claims 1-10 under 35 USC 101

Therefore, these rejections are expressly withdrawn.

3. Applicants' arguments, see Remarks, filed 11/30/2009, with respect to the rejection of claims 1, 3, 6, 11, 13 and 16 under 35 USC 102(b) and claims 2, 4, 5, 7-10, 12, 14, 15, and 17-20 under 35 USC 103(a) have been have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 6, 11, 13 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Oosawa (US 7,616,789 B2).

4. **Regarding claims 1 and 11**, Oosawa discloses a medical image diagnosis support device and method, comprising: a controller configured through a program of instructions, embodied in a computer readable medium, executable by the controller to include the following units (Fig. 12): an organ region setting unit for setting organ regions in medical images obtained by a medical imaging device (Col. 20, ln 7-15; See also Fig. 10 (P, P_c) - organ region is set to include regions that are similar between inputted image as well as stored normal images); a deformation degree calculating unit for calculating in an image a degree of deformation from normal shapes of the organ regions set by the organ region setting unit (Col 12, ln 33-39: P_{su} is the subtraction image which is the calculated degree of deformation from a normal shape); a reference value storing unit for storing a reference value of the normal shapes of the organ regions (Col. 12, ln 20-22: P_c is a normal structure reference value); a lesion detecting

unit for detecting existence of lesion of an organ region from amongst the organ regions set by the organ region setting unit from a result of comparing the reference value stored by the reference value storing unit with the degree of deformation being calculated by the deformation degree calculating unit (Col. 12, ln 40-43); and an informing unit for at least one of visually informing and auditorily informing the existence of the lesion detected by the lesion detecting unit (Col. 12, ln 27-32: output means).

5. **Regarding claims 3 and 13**, Oosawa discloses the medical image diagnosis support device and method of claims 1 and 11. Oosawa further discloses wherein the reference value storing unit stores a plurality of templates according to the degree of deformation calculated by the deformation degree calculating unit (Col. 18, ln 63-66: each inputted image "P" corresponds to a normal reference image "P_c" which is approximately identical and has an associated subtraction image "P_{su}" or deformation degree - the images or templates can subsequently be stored in association with each other).

6. **Regarding claims 6 and 16**, Oosawa discloses the medical image diagnosis support device and method of claims 1 and 11. Oosawa further discloses wherein the informing unit informs the existence of the lesion visually by displaying the lesion through colors or movement in displayed images (Col. 17, ln 33-51: pixel values are displayed as black, white and variation of scale in-between, the color identifies abnormal and normal tissue).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 4, 5, 7, 9, 12, 14, 15, 17 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oosawa in view of Greenberg et al. (US 6,301,498 B1: "Greenberg").

8. **Regarding claims 2 and 12**, while Oosawa discloses the medical image diagnosis support device and method of claims 1 and 11, he fails to disclose a bifurcation detecting unit for detecting bifurcation of the organ region; an unit for creating a plurality of cross-sections of the organ region diverged by the bifurcation detected by the bifurcation detecting unit; and a distance calculating unit for calculating a shortest distance of an opposed peripheral portion between each of the plurality of cross-sections, and wherein the lesion detecting unit detects the existence of the lesion in the organ region based on the shortest distance of the opposed peripheral portion between the plurality of the cross-sections.

Greenberg discloses a bifurcating detecting unit for detecting bifurcation of the organ region (Col. 10, lines 17-21); a unit for creating a plurality of cross-sections of the organ region diverged by the bifurcation detected by the bifurcation detecting unit (Fig. 6d); and a distance calculating unit for calculating a shortest distance of an opposed peripheral portion between each of the plurality of cross-sections (Col. 2, lines 36-42), and wherein the lesion detecting unit detects the existence of the lesion in the organ region based on the shortest distance of the opposed peripheral portion between the plurality of the cross-sections calculated by the distance calculating unit (Col. 3, lines 45-47).

While Oosawa's disclosure is detailed with specific reference to lung imagery, his method is more generally applied to the detection of any abnormal tissue that can be identified by finding a degree of deformation between a medical image of interest as

compared to a normal medical image of the same area of interest. Therefore, the elements of his invention can be implemented for any medical imaging of a tissue or organ whereby a subtraction image can be obtained to identify an area of interest.

Since examination of internal organs and other localized structures are available as per Oosawa's disclosure, then the examination of these could be specific to their featured characteristics. Oosawa teaches that "the area of the region, the shape of the region, and the like" can be employed to determine an abnormal area (Col. 18, ln 10-12). Since lesions, stenosis and the like are often characterized by constriction or narrowing of a structure under inspection (specific to Greenberg's examination of arteries), examination of the geometric attributes of the suspect region would be an obvious endeavor (Greenberg, Col. 3, lines 18-25). Oosawa doesn't specifically mention using cross-sectional images since his invention dealt with chest images, but examination of other internal organs was known in the art at the time of the invention, to frequently deal with cross-sectional images or "slices".

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Oosawa, a unit for detecting bifurcation of the previously calculated organ region; a unit for creating a plurality of cross-sections of the organ region diverged by the bifurcation detected by the bifurcation detecting unit; and a distance calculating unit for calculating a shortest distance of an opposed peripheral portion between each of the plurality of cross-sectional images, and wherein the lesion detecting unit detects the existence of the lesion in the organ region based on the shortest distance of the opposed peripheral

portion between the plurality of the cross-sectional images, calculated by the distance calculating unit, as suggested by Greenberg, in order to examine other internal structures other than the lungs.

9. **Regarding claims 4 and 14**, while Oosawa discloses the medical image diagnosis support device and method of claims 1 and 11, he fails to disclose wherein the deformation degree calculating unit includes: a cross-sectional image calculating unit for calculating cross-sectional images that are orthogonal to axial direction of the organ region; and an extracting unit for extracting a lumen and an exterior of the organ region from the cross-sectional images calculated by the cross-sectional image calculating unit and calculating a degree of deformation of the lumen and the exterior of the organ region extracted by the extracting unit.

Greenberg discloses a cross-sectional image calculating unit for calculating cross-sectional images that are orthogonal to axial direction of the organ region (Fig. 5A); and an extracting unit for extracting the lumen and an exterior of the organ region from the cross-sectional images calculated by the cross-sectional image calculating unit (Fig. 5E); and calculating a degree of deformation of the lumen and the exterior of the organ region extracted by the extracting unit (Col. 8, lines 40-54)

Therefore, for the same reasons as stated in the presentation of claims 2 and 12 (see above), it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Oosawa, the unit as outlined by Greenberg, for calculating the cross-sectional images that are

orthogonal to axial direction of the organ region; and an extracting unit for extracting the lumen and the exterior of the organ region from the cross-sectional images being calculated from the cross-sectional image calculating unit; and calculates the degree of deformation of the lumen and the exterior of the organ region being extracted by the extracting unit, in order to examine other internal structures other than the lungs.

10. **Regarding claims 5 and 15**, while Oosawa discloses the medical image diagnosis support device and method of claims 1 and 11, he fails to disclose an extracting unit for extracting a hollow viscera from the organ region; a notable region setting unit for setting a notable region of the hollow viscera extracted by the extracting unit; and an unit for creating cross-sectional images of the hollow viscera extracted by the extracting unit based on the notable region set by the notable region setting unit, and wherein the lesion detecting unit detects the existence of the lesion of the organ region based on degree of deformation of the cross-sectional images of the hollow viscera.

Greenberg discloses an extracting unit for extracting a hollow viscera from the organ region (Col. 5, lines 11-30); a notable region setting unit for setting a notable region of the hollow viscera extracted by the extracting unit (Col. 9, lines 19-24); and an unit for creating the cross-sectional images of the hollow viscera extracted by the extracting unit based on the notable region set by the notable region setting unit (Col. 9, lines 14-18), and wherein the lesion detecting unit detects the existence of the lesion of

the organ region based on the degree of deformation of the cross-sectional images of the hollow viscera (Col. 19, lines 13-16).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to include in the device and method as outlined by Oosawa, a unit for extracting the hollow viscera out of the organ region being set by the organ region setting unit; a notable region setting unit for setting the notable region of the hollow viscera being extracted by the extracting unit; and a unit for creating the cross-sectional images of the hollow viscera being extracted by the extracting unit based on the notable region being set by the notable region setting unit, and wherein the lesion detecting unit detects the existence of the lesion of the organ region based on the deformation degree of the cross-sectional images of the hollow viscera being created by the creating unit, as suggested by Greenberg, in order to facilitate the examination of other internal organs other than a lung.

11. **Regarding claims 7 and 17**, Oosawa discloses the medical image diagnosis support device and method according to claims 6 and 16. Oosawa also discloses a visual presentation that highlights the lesion candidate portions being detected by the lesion detecting unit on the images (Col. 18, ln 30-32: "rectangle" or "arrow"), but fails to disclose wherein the visual presentation is executed by displaying the cross-sectional images of the organ regions, and by highlighting lesion candidate portions detected by the lesion detecting unit on the cross-sectional images.

Greenberg discloses wherein the visual presentation is executed by displaying the cross-sectional images of the organ regions, and by highlighting lesion candidate portions detected by the lesion detecting unit on the cross-sectional images (Claim 11: unit for expressing the X-ray intensity for each X-ray image as lumen functions across an artery cross section).

Greenberg's teaching allows for discriminating the details of a region of interest in such a way that would facilitate identification of lesions of other organs other than the lungs. Lesions and stenosis of organs have geometric characteristics that a cross-sectional image would present in a more obvious manner. Highlighting the relevant areas in a cross-sectional image would even more so draw the attention of an operator to the area of interest.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the teachings of Greenberg to Oosawa in order to facilitate identification by an operator of the existence of lesions in a cross-sectional image.

12. **Regarding claims 9 and 19**, Oosawa discloses the medical image diagnosis support device and method according to claims 1 and 11, but fail to disclose a cross-section extracting unit for extracting cross sections from a feature quantity of a hollow viscera on the medical images obtained by the medical imaging device; a physical quantity calculating unit for calculating a physical quantity including radius, degree or circularity, and gravity point of the hollow viscera on the hollow viscera cross-sections

extracted by the extracting unit; an ROI calculating unit for calculating a region of interest based on the physical quantity calculated by the physical quantity calculating unit; a 3-dimensional image creating unit for creating 3-dimensional images of the hollow viscera from the medical images including the cross sections of the hollow viscera extracted by the cross section extracting unit within the region of interest calculated by the ROI calculating unit; and an image displaying unit for displaying the 3-dimensional images created by the 3-dimensional image creating unit.

Greenberg discloses a cross-section extracting unit for extracting cross sections from a feature quantity of the hollow viscera on the medical images obtained by the medical imaging device (Co1.5, lines 30-33: Greenberg does this using lumen functions.); a physical quantity calculating unit for calculating a physical quantity including radius, degree of circularity, and gravity point of the hollow viscera on the hollow viscera cross-sections extracted by the extracting unit (Col. 3, lines 19-25: analysis of a cross-sectional area could produce radius, degree of circularity as well as gravity point (understood to be a center point)) ; an ROI calculating unit for calculating a region of interest based on the physical quantity calculated by the physical quantity calculating unit (col. 3, lines 26-30); a 3-dimensional image creating unit for creating 3-dimensional images of the hollow viscera from the medical images including the cross sections of the hollow viscera extracted by the cross section extracting unit within the region of interest being calculated by the ROI calculating unit (Claim 1 : reconstructing the lumen functions to create a three-dimensional image); and an image displaying unit for displaying the

3-dimensional images created by the 3-dimensional image creating unit (Abstract: lines 7-8; see also Fig. 3A).

Analysis of organ and vessel shapes can indicate relevant conditions, such as lesions and stenoses. Cross-sectioning areas of interest in order to develop dimensional data with regards to an organ or vessel would facilitate an operator to visually identify possible lesions or stenoses.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to apply the teachings of Greenberg to Oosawa in order to calculate dimensional data of an area of interest by which an operator might identify lesions or stenoses.

Claims 8 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oosawa in view of Heilbrun et al. (U.S. Pub. No.: 20010039421 A1,"Heilbrun").

13. **Regarding claims 8 and 18**, Oosawa discloses all the limitations of claims 1 and 11. Oosawa further discloses informing the existence of a lesion to an examiner (Col. 18, ln 30-32: "rectangle" or "arrow") but fails to disclose wherein the informing unit informs the existence of the lesion auditorily by outputting it through voices and sounds, or a variance of the voices and sounds.

Heilbrun discloses informing auditorily by outputting it through voices and sounds (Page 8, lines 6-10). While Heilbrun's notification is regarding the position of

the operative portion of an instrument relative to structures of interest, it is the goal to notify the operator of relevant information that is important. In Heilbrun's invention, the relevant information that needs to be related to the examiner is the position of the operative portion of an instrument, while in Oosawa's invention, the relevant information is the notification of the location of abnormal tissue. Giving auditory notification to an operator of some type of event which is in the interest of the operator to notice is an obvious method that is used in many arts. A voice alert is an organized set of sounds relating to speech, therefore, the use of voice in itself is the use of sound

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the device and method of Oosawa, the step of informing auditorily by outputting it through voices and sounds as suggested by Heilbrun, in order to more effectively draw the attention of an operator to a specific area of relevance, such as the existence of a lesion.

Claims 10 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oosawa and Greenberg in view of Knoplioch (U.S. Patent Number: 6643533, "Knoplioch").

14. **Regarding claims 10 and 20**, while the combination of Oosawa and Greenberg disclose the limitations of claims 9 and 19, they fail to disclose the limitations of claims 10 and 20.

Knoplioch discloses a center-line calculating unit for calculating a center line of the hollow viscera based on the gravity point of the hollow viscera cross sections calculated by the physical quantity calculating unit (Col. *6*, lines 31-34), wherein the image display unit displays the center line calculated by the center-line calculating unit together with the 3-dimensional images being created by the 3-dimensional image creating unit (Col. 3, lines 22-24; with reference to Fig. 4 - See also: Col. 5, lines 18-23). Knoplioch's teaching allows for geometrical display of organs under scrutiny with reference to a centerline which would facilitate critical analysis of any objects of interest. Abnormalities of organs and vessels are often easily noticed with reference to shape and utilizing a reference plane or line such as a centerline, would facilitate determination of abnormalities which might be considered relevant.

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method and device of Oosawa and Greenberg, a center-line calculating unit for calculating a center line of the hollow viscera based on the gravity point of the hollow viscera cross sections calculated by the physical quantity calculating unit, wherein the image display unit displays the center line calculated by the center-line calculating unit together with the 3-dimensional images being created by the 3-dimensional image creating unit, as suggested by Knoplioch, in order to facilitate

visual determination by an operator of displayed abnormalities which might be considered relevant.

Conclusion

Applicants' amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS A. CONWAY whose telephone number is (571)270-5851. The examiner can normally be reached on Monday through Friday 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bella Matthew can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas A. Conway/
Examiner, Art Unit 2624

/Tom Y Lu/
Primary Examiner, Art Unit 2624